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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/879,329

Applicant(s)

SIGNER ET AL.

Examin r

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,10,12,14,15 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 2,3,7,9,11,13,16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1636

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 12 June 2001, which claims benefit of U.S. Provisional application 60/211,122 filed 12 June 2000. Claims 1-20 are pending and under consideration.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The declaration is not signed by the Inventors.

Claim Objections

Claims 18 and 20 are objected to because of the following informalities: There should be a verb after "plant cell" in line 1 of the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 8, 10, 12, 14, 15 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

Art Unit: 1636

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The instant claims are directed to a genetic construct comprising a negative selectable marker and method of using said genetic construct. The Guidelines for Written Description state, “The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art” (Federal Register, Vol. 66, No. 4, Column 1, page 1105). In the instant case, the negative selectable marker gene is a critical element of the claimed invention. The specification defines the negative selectable marker gene as any gene that encodes a protein that prevents the growth of a plant or plant cell on selective medium (paragraph [0028]). Thus the negative selectable marker of the claims encompasses any conditional selectable marker gene capable of preventing the growth of any plant or plant cell. Koprek *et al.* (1999) *Plant J.* 19 :719-726, teaches that a broad spectrum of negative selectable marker genes, which could be used in a wide variety of plant species was not conventional in the art at the time the instant application was filed. Koprek *et al.* teaches that some limited success had been achieved using genes such as

Art Unit: 1636

tms2, *aux2*, HSV-tk, cytochrome *P450* and *cod A* as negative selectable marker genes in dicotyledonous plants, and teaches that cytochrome *P450* and *cod A* can be used in barley (see especially page 719, column 2; the third full paragraph in the second column on page 721; and the paragraph bridging columns 1 and 2 on page 723). Thus, Koprek *et al.* teaches that, although negative selectable marker genes, as defined in the instant specification, were known in the art at the time of filing, they were limited in number and had a limited spectrum. Therefore, it is incumbent upon Applicant to disclose a representative number of negative selectable markers such that one of skill in the art would recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the species disclosed (see the Guidelines for Written Description, *Id.* at 1106, column 3).

The Guidelines for Written Description state: “when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus” (Federal Register, Vol. 66, No. 4, Column 3, page 1106). “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406” MPEP §2163(3)(a)(ii).

In the instant case, Applicant discloses two examples of negative selectable markers (i.e., *CodA* and *dh1A*). Beyond that, description of the negative selectable marker is limited to a

Art Unit: 1636

recitation of function with no correlation of structure and function. An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property, i.e., it encodes a negative selectable marker, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of negative selectable markers encompassed by the selectable marker of the claims. Therefore, only the described *CodA* and *dhIA* genes meet the written description provision of 35 U.S.C. §112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in the recitation of "the plant cell" in line 1. There is no antecedent basis for "the plant cell" in claim 4, from which claim 18 depends. Amending claim 18 to depend from claim 17 would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Selten *et al.*

U.S. Patent No. 6,051,431.

Selten *et al.* teaches a genetic construct which comprises a positive selectable marker gene and a negative selectable marker gene flanked by direct repeats of a gene of interest. In Figure 2, Selten *et al.* describes a gene replacement vector which comprises the admS selectable marker gene which is capable of both positive and negative selection (see especially the second and third full paragraphs in column 7). The gene replacement vector of Selten *et al.* further comprises direct repeats of a portion of the glaA gene, which flank the admS gene. As the direct

Art Unit: 1636

repeats of a gene of interest are not limited to comprising the full length gene of interest or an expressible portion of the gene of interest, the direct repeats of the *glaA* gene comprised by the gene replacement vector of Selten *et al.* meet the limitations of the direct repeats of the instant claims and the genetic construct of claim 1, as a whole, is anticipated by Selten *et al.*

Selten *et al.* further teaches a method of removing a selectable marker gene from a transformed eukaryotic cell (i.e., fungi) comprising transforming cells with the disclosed gene replacement vector, culturing cells in positive selection medium, transferring the transformed cells to negative selection medium and selecting cells that grow on negative selective medium (see especially the first full paragraph in column 3). Thus, Selten *et al.* teaches all of the limitations of the instant claim 4.

The genetic construct and method of using said genetic construct taught by Selten *et al.* are the same as those claimed in the instant application; therefore, the claims are anticipated by Selten *et al.*

Allowable Subject Matter

Claims 2, 3, 7, 9, 11, 13 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Art Unit: 1636


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms



**JAMES KETTER
PRIMARY EXAMINER**